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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,837	08/02/2006	Michael Crothers	833.012	6054

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EXAMINER	
MI, QIUWEN	
ART UNIT	**PAPER NUMBER**
1655	

NOTIFICATION DATE	DELIVERY MODE
02/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

Office Action Summary	Application No.	Applicant(s)	
	10/550,837	CROTHERS ET AL.	
	Examiner	Art Unit	
	Qiuwen Mi	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 12/21/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

Election/Restrictions

Applicant's election with traverse of claims 1-18 and the species *Ascomycotina* in the reply filed on 5/16/2007 is acknowledged.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As Belanger et al (US 5,443,981) teach a special technical feature of a crude membrane fraction of Fungus *Acremonium typhinum* which is reactive with BCA and the endoproteolytic activity is inhibited by the protease inhibitor PMSF (col 1, lines 60-67), therefore, there is no special technical feature in the application. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1., and therefore lack of unity of invention exists.

Applicant is reminded of the extensive literature search in biotechnology which is not co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims Pending

Claims 19-22 are cancelled. Claims 1-18 are pending. Claims 1-18 are examined on the merits.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 USC § 102 (b) as being anticipated by Belanger et al (US 5,443,981).

Belanger et al teach a crude membrane fraction of Fungus *Acremonium typhinum* (adjuvant, contains a fungal cell or fragment) exhibiting endoproteolytic activity which has a function of insect deterrence (thus a medicament) (col 1, lines 45-50), and the fraction is reactive with BCA (pharmaceutically active compound, peptide, having a hydrophilic moiety). The endoproteolytic activity is inhibited by the protease inhibitor PMSF (pharmaceutically active compound) (col 1, lines 60-67). Fig. 4 shows the SDS-PAGE analysis of endophyte-infected leaf sheath extract and BSA in the presence of a reductant or of inhibitors PMSF (col 3, 60-65). Since the reference does not mention that the crude membrane fraction of Fungus *Acremonium typhinum* is encapsulated, it is considered as a non-encapsulating adjuvant.

Therefore, the reference is deemed to anticipate the instant claim above.

Applicant argues that Belanger does not suggest that the At membrane fraction is the active element in insect deterrence or that is has other pharmaceutical properties (page 8, 1st paragraph), Belanger does not teach a fungal adjuvant.

The intended use of the composition does not further limit the composition. Since this is not a method of use, it does not matter what the composition or each component is used for. In addition, the above description has clearly indicated how each component met the claim limitations.

Claims 1-4, 7-12, and 18 are rejected under 35 USC § 102 (e) as being anticipated by Breton et al (US 2005/0069505), as evidenced by Molano et al (Distribution of chitin in the yeast cell wall, the Journal of Cell Biology, 85: 199-212, 1980)*.

Breton et al teach a composition for photoprotection of the skin (for use as a medicament) comprising at least one probiotic lactic acid (pharmaceutically active compound, having hydrophilic moiety) bacterium and at least one carotenoid or derivative (pharmaceutically active compound) (see Abstract). The composition further comprises yeast extract selected from *Ascomycotina* or *Saccharomyces caerevisae* (adjuvant) [0027]. Since the reference does not mention that the yeast extract (contains a fungal cell or fragment) is encapsulated, it is considered as a non-encapsulating adjuvant.

As evidenced by Molano et, chitin is distributed in yeast *Saccharomyces cerevisiae* cell walls (see Abstract).

Therefore, the reference is deemed to anticipate the instant claim above.

Applicant argues that the mere disclosure of yeast extract does not rise to the disclosure of "a non-encapsulating adjuvant, wherein the adjuvant comprises a fungal cell or a fragment thereof" as required by claim 1 (page 8, 4th paragraph).

Since the yeast extract selected from *Ascomycotina* or *Saccharomyces caerevisae* (adjuvant), inherently contains a fungal cell or fragment, and there is no mentioning that the yeast extract is encapsulated, thus it is considered as a non-encapsulating adjuvant, thus met the claim requirement.

Applicant also argues that Breton does not disclose the use of a fungal cell or fragment thereof necessarily would act as an adjuvant to the pharmaceutically active compound (page 9, 2nd paragraph).

Again, the intended use of the composition does not further limit the composition. Since this is not a method of use, it does not matter what the composition or each component is used for.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, and 7-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton et al (US 2005/0069505) in view of Modi (US 6,221,378), as evidenced by Molano et al (Distribution of chitin in the yeast cell wall, the Journal of Cell Biology, 85: 199-212, 1980)*.

Breton et al teach a composition for photoprotection of the skin (for use as a medicament) comprising at least one probiotic lactic acid (pharmaceutically active compound, having hydrophilic moiety) bacterium and at least one carotenoid or derivative (pharmaceutically active compound) (see Abstract). The composition further comprises yeast extract selected from *Ascomycotina* or *Saccharomyces caerevisae* (adjuvant) [0027]. Since the reference does not mention that the yeast extract (contains a fungal cell or fragment) is encapsulated, it is considered as a non-encapsulating adjuvant.

As evidenced by Molano et, chitin is distributed in yeast *Saccharomyces cerevisiae* cell walls (see Abstract).

Breton et al do not teach paracellular pathway, encapsulation, and claimed amount of chitin/chitosan.

Modi teaches protein drug was encapsulated in mixed micelles which allows opening of paracelular junctions with high degree of protease activity preserved and protecting molecules from premature degradation in the hostile acidic and proteolytic GI environment (*in vivo*), and

overcoming the problem of the bitter taste and irritation of the drug (col 2, lines 58-67; col 3, lines 1-5).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the encapsulation technique to enhance the paracelular permeability of Modi in Breton et al since Modi teaches that the delivery system has high degree of protease activity preserved and it can protect molecules from premature degradation in the hostile acidic and proteolytic GI environment (*in vivo*), and it overcomes the problem of the bitter taste and irritation of the drug (col 2, lines 58-67; col 3, lines 1-5). Since the invention of Modi yielded beneficial results in drug delivery system, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

Applicant argues that there is no suggestion that a fungal cell or a fragment thereof could be used as an adjuvant to a pharmaceutical active compound (page 10, last paragraph).

As indicated above, the intended use of the composition does not further limit the composition. Since this is not a method of use, it does not matter what the composition or each component is used for.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

MICHAEL MELLER
PRIMARY EXAMINER